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A dynamic aortic patch as a permanent mechanical auxiliary ventricle: Experimental studies

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Among mechanical methods for long-term circulatory assistance, those based on phase-shift pumping, i.e., the introduction of external energy into the vascular tree during the diastolic phase of the cardiac cycle, have been of particular interest in this laboratory. Experimental and clinical experience with the U-shaped mechanical auxiliary ventricle has been reported.[4, 7-10, 15] Another configuration for the auxiliary ventricle was suggested by experiences with intra-aortic phase-shift balloon pumping, a method for ventricular support in which a polyurethane pumping chamber is passed into the descending thoracic aorta and inflated with helium during cardiac diastole. The balloon pumping system has proved capable of supporting the circulation of subjects in experimental acute left ventricular failure and of patients in cardiogenic shock refractory to medical therapy.[13, 16]

In principle, an implantable pumping chamber situated in the descending thoracic aorta and having a shape and stroke volume similar to those of the balloon pump might provide comparable hemodynamic effects. An implantable device, however, could be used for permanent circulatory assistance. It would interfere minimally with physiologic blood flow. The blood interface might consist of a material favoring the development of a living lining of endothelial cells and thereby reduce the severity of the clotting problem.[5] The surgical implantation of the device, moreover, would not be so demanding as that required for the U-shaped auxiliary ventricle.[10]

Studies of a dynamic aortic patch were undertaken to determine whether the device has these characteristics. The results of preliminary investigations are reported here.

MATERIALS AND METHODS

Prosthesis. The dynamic aortic patch consists of a flexible bladder fabricated from reinforced 0.1778 mm. silicone rubber,* a pliant, 15 cm. silicone rubber gas conduit emerging from one surface of the bladder, and covering materials. Its dimensions and stroke volume depend on the size of the aorta into which it is to be implanted and on the stroke volume of the subject's left ventricle.

As used for experiments on dogs weighing 20 to 25 kilograms, the bladder (Fig. 1) measured 9 cm. along the long axis and 2.2 cm. in width. Its sides were parallel to within 1.1 cm. of the ends, which are pointed (Fig. 1). Seen in cross section through the longitudinal axis, the implanted bladder was curved so as to cover 90 to 120 degrees of a circle. The bladder could be inflated to

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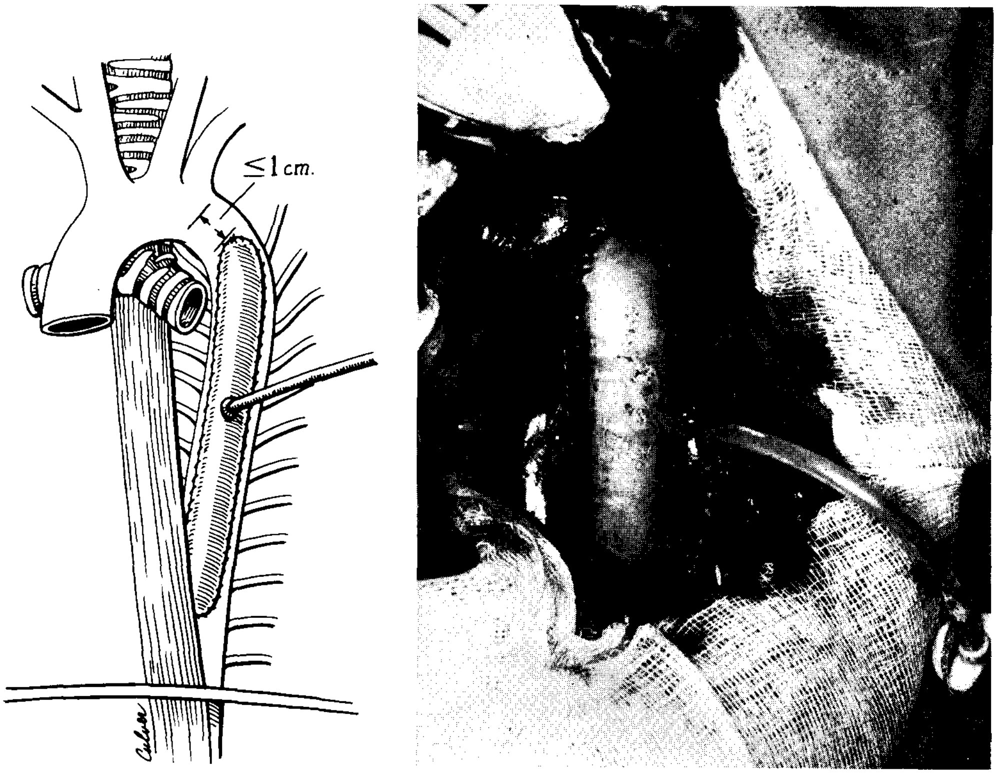

Fig. 1. Diagram and photograph of dynamic aortic patch implanted in descending thoracic aorta.

volumes of 12 to 15 c.c. at pressures of 2 to 3 p.s.i. For the blood interface, various materials of the same dimensions were applied to the concave surface of the bladder: 0.1778 mm. thickness silicone rubber, Dacron shirt material, pericardium backed with silicone rubber, and ironed woven Dacron arterial graft. Larger or smaller units were used when appropriate.

Surgical procedure. The dogs were anesthetized with Diabutal (30 mg. per kilogram, and a myorelaxant (Anectine) was given. A Bird respirator was used for artificial ventilation. Through a sixth left intercostal space incision the descending thoracic aorta was dissected free from the subclavian artery to the diaphragm.

Three methods were used to interrupt blood flow through the aorta while the patch was being sutured into place: cross-clamping, with occlusion of 5 to 7 pairs of intercostal arteries; shunting of blood from the subclavian artery to the left or right femoral artery without use of a pump; and side clamping by means of a 7 cm. De Bakey tangential occlusion clamp.

An incision into the aorta of the same length as the prosthesis was made, and suturing of the device to the intima of the vessel was started. After the first 4 to 5 cm. of the graft was sutured into place, the clamp was repositioned and the implantation completed.

After immediate bleeding was controlled, blood loss was replaced with fresh ACD (acid citrate dextrose) blood (maximally, 500 c.c.), and the thoracotomy incision was closed. The end of the gas conduit was passed through the fifth intercostal space to a subcutaneous pocket near the thoracotomy incision. Postoperatively, penicillin was administered for 5 days.

Driving and monitoring. The dynamic aortic patch was driven by helium. The flow from an extracorporeal reservoir to the gas conduit was regulated by a solenoid valve controlled by a modified dual-beam oscilloscope.* One beam was triggered by either the R wave of the electrocardiogram or the left ventricular pressure curve; the other beam regulated the time delay required for optimal functioning of the unit. The time delay from the onset of the R wave to inflation of the pumping chamber ranged between 175 and 200 msec.

During hemodynamic support with the dynamic aortic patch pressures were recorded with a Statham strain gauge†: left ventricular pressure via a Silastic tube inserted through a stab incision; left femoral artery pressure via a cannula inserted through a small incision in the groin; and central aortic pressure via a cannula inserted into the aortic arch through the carotid artery. The electrocardiogram was also recorded. All parameters were monitored with a Sanborn 4-channel recorder.‡

Experiments. In Group 1 (20 dogs weighing 18 to 23 kilograms) studies, various materials for the blood interface were implanted. The patches were 7 cm. in length but varied from 1 to 3 cm. in width. Angiographic studies were performed in two animals. All but three animals died or were killed at various postoperative intervals for autopsy.

In Group 2 (11 dogs weighing 21 to 27 kilograms) experiments, dynamic aortic patches of varying sizes were implanted. In eight acute experiments in this group, the short-term hemodynamic function of the prosthesis was studied. In three animals long-term pumping was attempted.

In Group 3 (23 dogs weighing 18 to 31 kilograms) experiments, dynamic aortic patches measuring 9 by 2.2 cm. with an inner lining of ironed Dacron arterial graft were implanted for evaluation of long-term patency and for observation of hemodynamic effects two weeks after operation (two cases).

*Tektronix 565, Tektronix, Inc., Beaverton, Ore.

†Model P23Db, Statham Instrument Co., Los Angeles, Calif.

‡Model 76-4-1, Sanborn Co., Waltham, Mass.

RESULTS

Group 1. Three dogs were well at the time of writing, 9, 8½, and 8½ months, respectively, after operation. Necropsy examination of the remaining dogs in this group disclosed that the aorta was not occluded by clot formation in any case. Macroscopic examination never disclosed infarction of the abdominal organs in these 17 animals. In the first 11 experiments, in which 7 by 3 cm. patches were implanted, clotting along the wall, filling the "aneurysmatic" portion of the aorta produced by implantation of the material, was observed in two instances in which Dacron shirt material was used. In three instances (two silicone rubber patches, one of pericardium), small clots in the distal portion of the patch or incomplete formation of a layer of cells over the implant was seen. Only units fabricated of woven Dacron arterial graft or pericardium were free of clotting of this type.

In nine experiments, an attempt to prevent clot formation was made by minimizing the dilatation of the aorta produced by implantation of the patch, thereby permitting a nearly normal flow rate through the vessel. Patches of Dacron shirt material 1 to 1.5 cm. in width were implanted. At autopsy clotting could be seen only along the distal part of the patch in three instances. In the six other instances no clotting was seen.

Group 2. The results of the first three experiments indicated that patches with a stroke volume of less than 12 c.c. are not able to support the circulation adequately. To fabricate units of larger stroke volume, it was necessary to use a wider patch, since the maximal length of the unit in dogs weighing 21 to 25 kilograms was 9 cm. But the Group 1 results indicated that patches of more than 1.5 cm. width tended to clot. We resolved this problem by implanting slightly larger patches (2.2 by 9 cm.) with the pumping chambers expanded during the inactive phase. With this method, the cross-sectional area of the aorta was increased

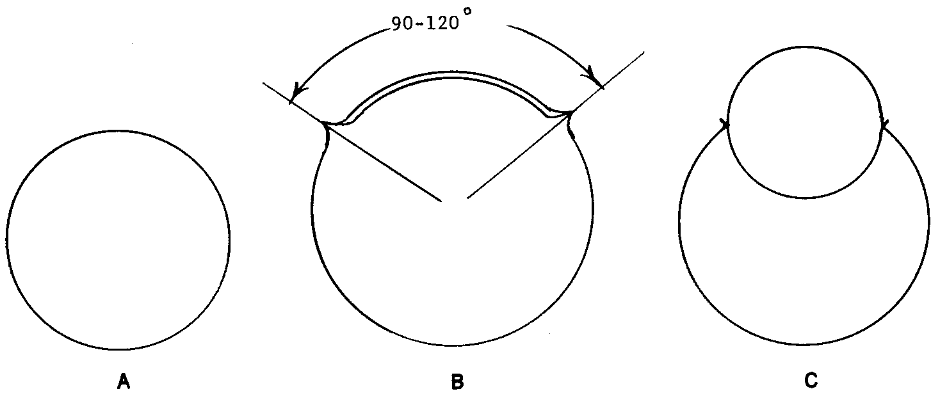

Fig. 2. Diagrammatic representation of relation of dynamic aortic patch to aorta. *A,* Cross section of aorta. Circumference = 6.28 cm.; area = 3.14 $cm.^2$ *B,* Cross section of aorta with dynamic patch in situ but not inflated. Circumference = 8.28 cm.; area = 5.46 $cm.^2$ *C,* Cross section of aorta with dynamic patch inflated. Circumference of patch = 4.4 cm.; area = 1.59 $cm.^2$ Circumference of aorta = 7.66 cm.; area = 3.70 $cm.^2$

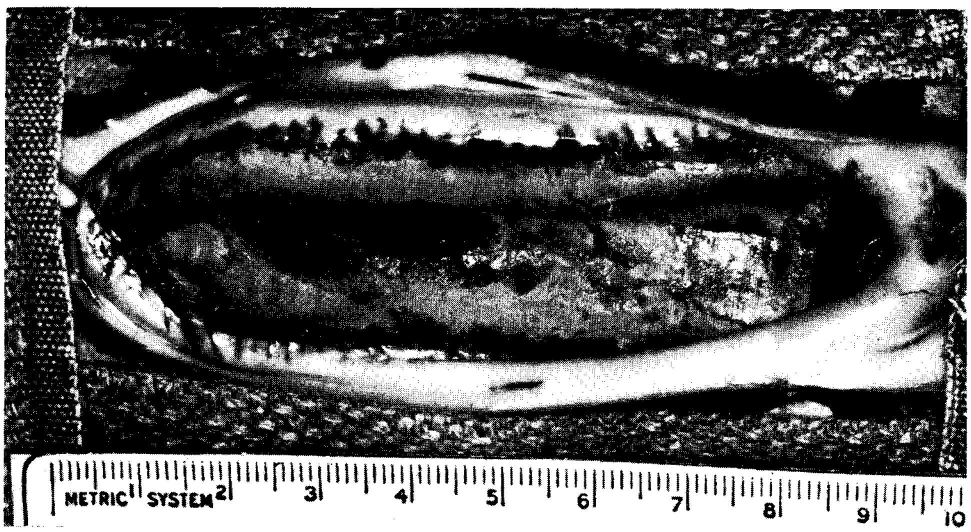

Fig. 3. Inner surface of aorta and of dynamic aortic patch with woven Dacron arterial graft lining 39 days after operation.

only slightly (Fig. 2). In normal adult dogs, i.e., animals not in induced ventricular failure, we obtained hemodynamic results comparable to those produced by the phase-shift balloon pump[16] or the mechanical auxiliary ventricle in similar animals. A decrease in left ventricular peak systolic pressure of 14.2 percent (range, 10 to 21 percent) and an increase in diastolic central aortic pressure of 17 percent (range, 8 to 25 percent) were recorded.

In three experiments long-term pumping was begun immediately after implantation. In the first experiment, the dog died of acute bleeding after 14 hours' continuous pumping. Several infarctions in abdominal organs were seen at autopsy. To avoid rupture of the aorta due to pumping, as seen in this experiment, we used a double suture technique with a backing of Dacron felt on the exterior surface of the vessel in all subsequent implantations. In each of the next two experiments, pumping for 26 hours was performed without rupture of the aorta. Again, however, infarctions in the abdominal organs were seen in both cases. In the long-term pumping experiments, free plasma hemoglobin levels did not exceed 100 mg. percent. Both dogs died of prolonged anesthesia and operative trauma.

Group 3. The average survival time in the 23 dogs was 14.63 days (range, 2 to 77 days). One dog is still alive at this writing, 7 months after operation. Postoperative paraplegia was a relatively frequent (4 dogs or 17 percent) complication in this group, despite the use of side clamping.

Of 22 dogs in this group in which postmortem examinations were performed, 13 (59 percent) were free of clots. The quality and strength of the cellular formation over the inner surface of the patch depended upon survival time. In the longest survivor (77 days) studied at necropsy, the surface of the patch was smooth, clot-free, and strongly adherent to the underlying Dacron. In three dogs (13.6 percent) we found small clots in the distal part of the patch (Fig. 3). Among the six remaining dogs (27 percent) there was extensive clotting in two in which the pumping chamber had not been inflated while the unit was not in use during the postoperative period. In the third case a severe intrathoracic infection associated with clots and infection in the suture line was found. In the fourth case, intermittent pumping for 10 days was performed. The animal succumbed from empyema and bleeding from the suture line. In the last two cases unexplained clot formation was seen.

Intrathoracic and wound infections (7 dogs, 31.8 percent) accounted for the greatest number of the deaths in this group. Five dogs (22.7 percent) died of pneumonia. Paraplegia followed by infection caused the deaths of three animals (13.6 percent), bleeding, of two dogs (9 percent), postoperative respiratory insufficiency, of one dog, and heart failure, of one dog.

Two dogs in this group underwent pumping starting on the fourteenth and seventeenth days after implantation. Pumping was performed for 1 hour every day for 8 and 10 days. One dog died on the eighth day after pumping was started. At autopsy extensive clotting on the Dacron inner lining and numerous infarctions in spleen, both kidneys, and the small intestine were found (Fig. 4). There was no embolization at the bifurcation of the aorta. In the other dog, a cineangiogram taken on the first day of pumping showed the aorta to be patent and the patch to function well. After 10 days

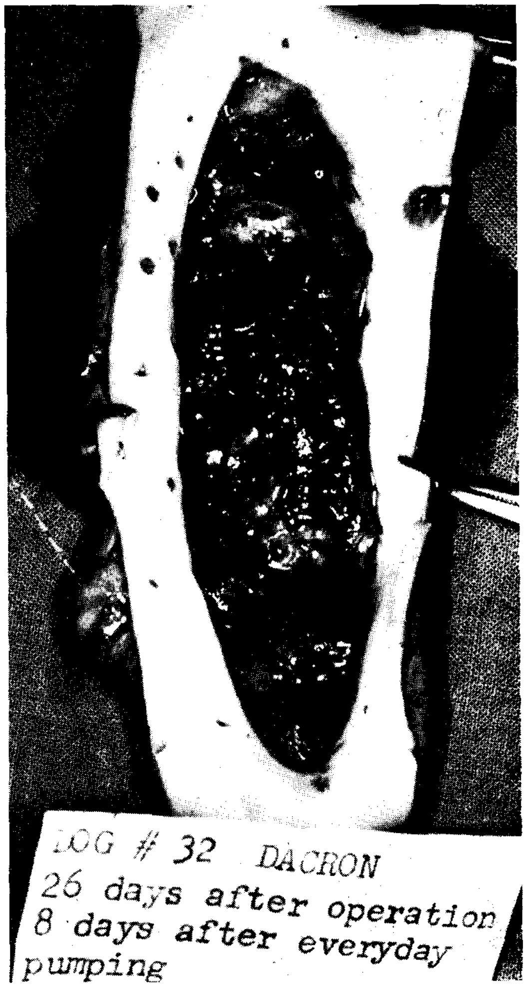

Fig. 4. Inner surface of aorta and of dynamic aortic patch with woven Dacron arterial graft lining 26 days after operation. On seventeenth day after implantation, pumping, 1 hour daily, was begun and continued every following day for 8 days.

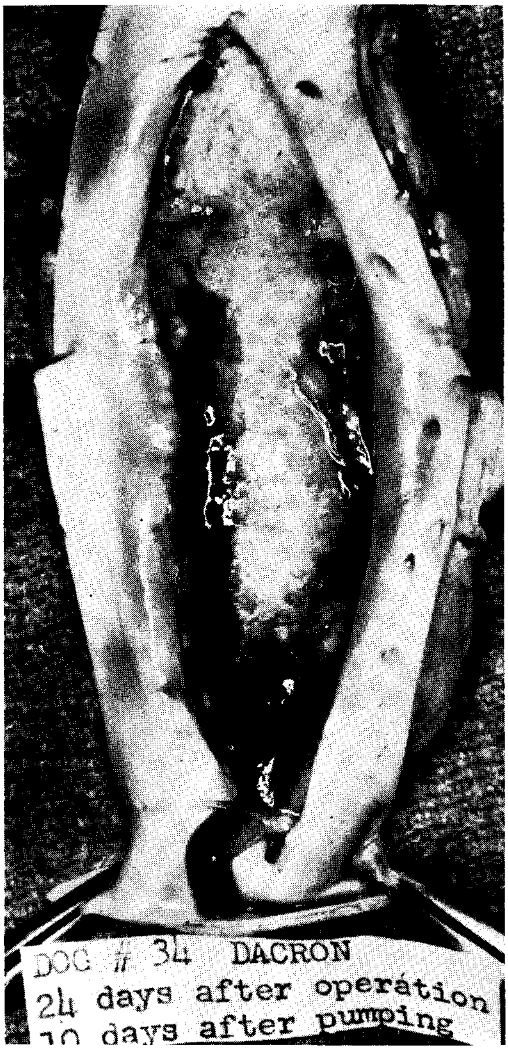

Fig. 5. Inner surface of aorta and of dynamic aortic patch with woven Dacron arterial graft lining. Daily pumping for 1 hour was started on fourteenth day after implantation. No infarctions in periphery were found.

of daily pumping, the animal died of an intrathoracic infection that had extended from the helium conduit (Fig. 5).

DISCUSSION

All hemodynamically effective prostheses for chronic or permanent cardiac assistance—left ventricular bypass,[13] counterpulsating,[3] or phase-shift devices[2, 11, 15, 16]—require construction of an extravascular pathway or introduction of a pumping chamber into the vascular system. Either procedure changes the characteristics of blood flow and requires that artificial materials of relatively large surface area be in continuous contact with the blood. The risk of clot formation is therefore increased.[12, 14]

In our approach, we sacrificed a measure of hemodynamic effectiveness, which appears to be a function of distance of the prosthesis from the aortic valve, for relative freedom from clot formation. Following the model of the intra-aortic phase-shift balloon pump, we used a portion of the descending thoracic aorta with a small area of artificial material as a pumping chamber.

An ideally athrombogenic material for the blood interface of vascular prostheses has not been devised. We elected to use a porous material, which would favor the eventual growth of a living endothelial lining, as has been done in blood vessel reconstruction.[6] After preliminary studies, we selected woven Dacron arterial graft for this purpose. The elasticity of this material is relatively stable,[1] and ample experience in vascular surgery has shown that it accepts the ingrowth of tissue from the surrounding aorta. There were no junctions of different nonbiologic substances in the blood interface of the prosthesis. This increased the probability that the fibrin layer formed on the inner surface after implantation would be converted into tissue.

The results indicated that if pumping was attempted 2 weeks after implantation, the developing cellular surface was damaged, and the rough surface that remained was the site of thrombus formation. In addition, numerous abdominal infarctions were seen. In the present studies we did not obtain data establishing the length of time required for growth of a sufficiently strong surface. This problem is currently under investigation. In clinical application, during the period in which the vascular surface is developing, the failing heart might be supported by intra-aortic phase-shift balloon pumping.

To evaluate the hemodynamic function of the dynamic aortic patch, we studied dogs in which heart failure had not been induced. Schilt and associates[16] reported that phase-shift balloon pumping reduced left ventricular peak systolic pressure by 7.3 to 13.3 percent. The changes in this parameter effected by the dynamic aortic patch were comparable to those achieved with balloon pumping. Since the stroke volume, energy source, position in the descending aorta, and timing of the inflation-deflation cycle of the pumping chamber are closely similar for the two methods of circulatory assistance, it is reasonable to expect that the effect of pumping on other hemodynamic parameters in animals in experimental left ventricular failure would also prove comparable.

Although the preliminary experiences with the dynamic aortic patch are encouraging, a number of questions must be considered in subsequent studies. Thus, we have not established the safety of the suture technique for implantation of the unit in diseased aortas. The greatest risk associated with implantation of the patch is intrathoracic infection, which may originate at the site where the driving tube leaves the body. Prevention of such infections is a problem in connection with all types of chronic artificial heart devices and was not considered in the present series of experiments. From the standpoint of safety of the surgical procedure, it is necessary to avoid ischemia of the spinal cord during implantation of the dynamic aortic patch. If pressures in the aorta are less than 60 to 70 mm. Hg below the level of the side clamp, the lower part of the body should be protected by means of bypass.

CONCLUSION AND SUMMARY

A dynamic aortic patch was studied in 54 experiments in mongrel dogs. Cigar-shaped silicone rubber pumping chambers of 12 to 15 c.c. stroke volume were implanted in the descending thoracic aorta just below the origin of the subclavian artery. The commonest complications of the implantation procedure were paraplegia, intrathoracic infection, and bleeding. The use of side clamping and a double suture technique helped to prevent the first and last of these difficulties.

Preliminary experiments were performed to select a material for the inner lining of the prosthesis. Among pericardium, silicicone rubber, Dacron shirt material, and woven Dacron arterial graft, the latter material proved best suited for the blood interface.

To obtain a stroke volume of 12 to 15 c.c. in 20 kilogram dogs, units 9 cm. in length and 2.2 cm. in width were fabricated. During inactivity, the pumping chamber was inflated so as to approximate the caliber of the intact aorta. In 23 experiments, a well-developed pseudointimal cellular surface was obtained in 15 animals. However, when hemodynamic studies were started early, either directly after implantation or 2 weeks later, there was interference with the development of the pseudointimal surface.

Effects of pumping on hemodynamic parameters in normal dogs were comparable to those in similar animals undergoing intra-aortic phase-shift balloon pumping. The stroke volume, energy source, location in the vascular system, and timing of the inflation cycle of the pumping chamber are closely similar for the two methods of circulatory support. It therefore seems reasonable to expect that the effects of hemodynamic support with the dynamic aortic patch on parameters not evaluated in these experiments resemble those obtained with balloon pumping.

These findings suggest that the dynamic aortic patch is a promising experimental configuration of the mechanical auxiliary ventricle in which a reduced incidence of thrombus formation may be obtained at the expense of relatively slight decrease in hemodynamic effectiveness.

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